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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,482	11/08/2001	David W. Morris	529452500124	2512

7590

07/12/2005

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/052,482

Applicant(s)

MORRIS ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 16 and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 608 (claims 15, 16 and new claims 20-22) in the reply filed on April 28, 2005 is acknowledged. The traversal is on the ground(s) that "... searching more than one invention would not constitute a serious burden", see page 4 of Remarks submitted April 28, 2005. This is not found persuasive because clearly different searches and issues are involved in the in the examination of different antibodies that bind and recognize structurally distinct conformations of proteins encoded by different and distinct polynucleotides. Moreover, Applicants have cancelled claims directed to other inventions rendering these arguments moot. For the reasons stated above the restriction requirement is deemed to be proper and is adhered to. Applicant is reminded that the policies set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86 will be followed.

However, the policies set forth in the Commissioner's Notice of February 28, 1996 published on March 26, 1996 at 1184 O.G. 86 will be followed. Method claims limited to the scope of the allowable product claims will be rejoined and examined at the time the product claims are indicated as being allowable. The requirement is still deemed proper and is therefore made FINAL.

The requirement is still deemed proper and is therefore made FINAL.

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2. Claims 15, 16 and 20-22 are pending.

Claims 15 and 16 have been amended.

Claims 20-22 have been added.

Claims 1-14 and 17-19 have been cancelled.

Claims 15, 16 and 20-22 are examined on the merits.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 120 is acknowledged. However, the continuation in part (CIP) applications upon which priority is claimed fails to provide adequate support for the claims, namely SEQ ID NO: 160-162. The Examiner has reviewed abandoned CIP applications, 09/747,377 and 09/798,586 for the said sequences and they do not seem to be of record in these two applications. Accordingly, the examined claims are granted the effective filing date of the instant application, November 8, 2001.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under

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the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 15, 16 and 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2003/0224460 A1 (filed September 24, 2001). Sequence 158 of the patent application publication is a lymphoma associated (LA) polynucleotide sequence that is 100% sequence identical to Applicants' SEQ ID NO: 162, see attached database sheets. This polynucleotide would encode the same polypeptide as Applicants' SEQ ID NO: 162. It follows that the said polypeptide would be bound by the disclosed LA antibodies (i.e. Fab, Fab₂, bispecific, single chain, monoclonal, polyclonal and chimeric antibodies), see sections 0302-0310. The antibodies of the disclosed invention are conjugated to a therapeutic moiety, see page 26, sections 0324 and 0325. The said antibodies specifically bind to the encoded polypeptide

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within a preferred range being 10^{-7} – 10^{-9} M⁻¹, see page 26, section 0327. The patent application publication discloses the compounds of the invention within pharmaceutical compositions, see page 33, columns 0409 and 0410.

6. Claims 15, 16, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 5,618,693 (issued April 8, 1997). Sequence 1 of the patent teaches a polynucleotide sequence that is 80.27% sequence homologous to Applicants' human coding sequence of STAT-5B, SEQ ID NO: 162, see attached database sheets. The polynucleotide sequence of the patent encodes a STAT-5B polypeptide that is specifically bound by human Stat 5-specific antibodies with an equilibrium constant preferably at least about 10^{-8} , which is within Applicants' range of 10^{-7} – 10^{-9} M⁻¹, see column 4, lines 1-8 and lines 15-19. Compositions of the invention may be comprised within physiologically acceptable carriers for therapeutic uses, see bridging columns of 9 and 10.

7. Claims 15, 16, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent number 5,618,693 (issued April 8, 1997). Sequence 1 of the patent teaches a polynucleotide sequence that is 80.27% sequence homologous to Applicants' human coding sequence of STAT-5B, SEQ ID NO: 162, see attached database sheets. The polynucleotide sequence of the patent encodes a STAT-5B polypeptide that is specifically bound by human Stat 5-specific antibodies with an equilibrium constant preferably at least about 10^{-8} .

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which is within Applicants' range of 10^{-7} – 10^{-9} M⁻¹, see column 4, lines 1-8 and lines 15-19. Compositions of the invention may be comprised within physiologically acceptable carriers for therapeutic uses, see bridging columns of 9 and 10.

8. Claims 15, 16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Silva et al. (Molecular Endocrinology 10: 508-518, 1996). Silva discloses a polynucleotide sequence that is 99.7% sequence homologous to Applicants' human coding sequence of STAT-5B, SEQ ID NO: 162, see attached database sheets, Accession number U48730 and Silva, page 513, Figure 6A. The polynucleotide sequence of Silva encodes a STAT-5B polypeptide that is specifically bound by an anti-STAT5 polyclonal antibody, see page 509, Figure 1, and Results section in both columns; page 510, Figure 2; page 512, column 2, middle of said column. Although Silva does not specifically recite the binding constant between the disclosed antibody and the protein encoded by the DNA of Silva which is homologous to SEQ ID NO: 162 is 10^{-7} – 10^{-9} M⁻¹ this limitation would be an inherent quality of the disclosed antibody in light of the fact it acts in the same manner as Applicants' claimed product.

9. Claims 15, 16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (J. Biol. Chem. 271(18): 10738-10744, May 3, 1996). Lin discloses a polynucleotide sequence that is 100% sequence homologous to Applicants' human coding sequence of STAT-5B, SEQ ID NO: 162, see attached

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database sheets, Accession number U47686. The polynucleotide sequence of Silva encodes a STAT-5B polypeptide that is specifically bound by an anti-STAT5 polyclonal antibody, see page 10740, Figure 1; Lin abstract; page 10739, column 1, Peptides...section; page 10741, column 2, Figure 4 caption. Although Lin does not specifically recite the binding constant between the disclosed antibody and the protein encoded by a polynucleotide that is the same as SEQ ID NO: 162 is $10^{-7} - 10^{-9} \text{ M}^{-1}$ this limitation would be an inherent quality of the disclosed antibody in light of the fact it acts in the same manner as Applicants' claimed product.

10. Claims 15, 16 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Santa Cruz Biotechnology, Inc. (1998/199 catalog, page 159), as evidenced by Silva et al. (Molecular Endocrinology 10: 508-518, 1996). Santa Cruz Biotechnology discloses a Stat5b polyclonal antibody, catalog number sc-836, which was implemented in the *in vitro* studies of Silva, see preceding rejection. The antibody is reactive with the amino terminus of the human sequence, see characteristics listed on the section titled "Stat5b (N-20): cat# sc-836". Although the catalog does not specifically recite the binding constant between the disclosed antibody and the protein encoded by the sequence of Silva (homologous to SEQ ID NO: 162) is $10^{-7} - 10^{-9} \text{ M}^{-1}$ this limitation would be an inherent quality of the disclosed antibody in light of the fact it acts in the same manner as Applicants' claimed product.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 15, 16 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent number 5,618,693 (issued April 8, 1997), in view of U.S. Patent Application Publication number 2003/0224460 A1 (filed September 24, 2001). The teachings of the patent have been presented in the 102(e) and 102(b) rejections. The patent does not teach that the antibodies are Fab, Fab₂, bispecific, single chain, monoclonal and chimeric antibodies and the antibodies are conjugated to a therapeutic moiety.

However, the U.S. patent application publication teaches antibodies (i.e. Fab, Fab₂, bispecific, single chain, monoclonal, polyclonal and chimeric antibodies) that specifically bind to STAT5B can be conjugated to a therapeutic moiety, such as a cytotoxic agent. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of both references to make additional types of antibodies and modulate those said antibodies for implementation in *in vitro*, as well as *in vivo* assays. The antibodies could be used to assess antigen/antibody specificity, recognition of antigen determinants and implication of the antigen and antibody in diagnostics or other immunological techniques. One of ordinary skill in the art

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would have been motivated to do so with a reasonable expectation of success by teachings in both the references that antibodies are useful for screening assays, antigen characterization, as well as tools for diagnosis and treatment, see patent, column 4, lines 1-9 and see patent application, page 23, section 0302 and 0303; page 24, section 0307; page 26, sections 0324 and 0325.

13. Claims 15, 16 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silva et al. (Molecular Endocrinology 10: 508-518, 1996), in view of U.S. Patent Application Publication number 2003/0224460 A1 (filed September 24, 2001). The teachings of Silva have been presented in the 102(b) rejection. Silva does not teach that the antibodies are Fab, Fab₂, bispecific, single chain, monoclonal and chimeric antibodies and the antibodies are conjugated to a therapeutic moiety.

However, the U.S. patent application publication teaches antibodies (i.e. Fab, Fab₂, bispecific, single chain, monoclonal, polyclonal and chimeric antibodies) that specifically bind to STAT5B can be conjugated to a therapeutic moiety, such as a cytotoxic agent. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of both references to make additional types of antibodies and modulate those said antibodies for implementation in *in vitro*, as well as *in vivo* assays. The antibodies could be used to assess antigen/antibody specificity, recognition of antigen determinants and implication of the antigen and antibody in diagnostics or other immunological techniques. One of ordinary skill in the art

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would have been motivated to do so with a reasonable expectation of success by teachings in both the references that antibodies are useful for screening assays, antigen characterization, as well as tools for diagnosis and treatment, see Silva entire article particularly page 516, column 1 and see patent application, page 23, section 0302 and 0303; page 24, section 0307; page 26, sections 0324 and 0325.

14. Claims 15, 16 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al. (J. Biol. Chem. 271(18): 10738-10744, May 3, 1996), in view of U.S. Patent Application Publication number 2003/0224460 A1 (filed September 24, 2001). The teachings of Lin have been presented in the 102(b) rejection. Silva does not teach that the antibodies are Fab, Fab₂, bispecific, single chain, monoclonal and chimeric antibodies and the antibodies are conjugated to a therapeutic moiety.

However, the U.S. patent application publication teaches antibodies (i.e. Fab, Fab₂, bispecific, single chain, monoclonal, polyclonal and chimeric antibodies) that specifically bind to STAT5B can be conjugated to a therapeutic moiety, such as a cytotoxic agent. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of both references to make additional types of antibodies and modulate those said antibodies for implementation in *in vitro*, as well as *in vivo* assays. The antibodies could be used to assess antigen/antibody specificity, recognition of antigen determinants and implication of the antigen and antibody in

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diagnostics or other immunological techniques. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in both the references that antibodies are useful for screening assays, antigen characterization, as well as tools for diagnosis and treatment, see entire Lin article particularly page 10741, Figure 4 and see patent application, page 23, section 0302 and 0303; page 24, section 0307; page 26, sections 0324 and 0325.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 6:30 am to 5:30 pm with alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER



Alana M. Harris, Ph.D.
06 July 2005